

## **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

### **Potential Occlusion of Individually Sold GRIPPER® Needles and GRIPPER® Needles Within PORT-A-CATH® Trays**

<b>Affected Devices:</b>	<b>Individual GRIPPER® Needles and PORT-A-CATH® Trays Containing GRIPPER® Needles.</b>
<b>Type of Action:</b>	<b>Removal</b>
<b>Date:</b>	<b>11 July, 2019</b>
<b>Attention:</b>	<b>Clinical Users of, and Distributors of affected GRIPPER® Needles and PORT-A-CATH® Trays containing GRIPPER® Needles</b>
<b>Affected Devices:</b>	<b>Individual GRIPPER® Needles manufactured between June 11, 2018 - February 21, 2019 and PORT-A-CATH Tray models/lots listed in Attachment 2.</b>

Dear Customer,

The purpose of this Field Safety Notice (FSN) is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action (FSCA) for specific GRIPPER® needles and specific PORT-A-CATH® Trays containing affected GRIPPER® needles.

#### **REASON FOR FIELD SAFETY CORRECTIVE ACTION:**

Smiths Medical became aware that certain individual GRIPPER® Needles, which were manufactured between 11 June 2018 through 21 February 2019, including those that are provided in certain PORT-A-CATH® Trays, may contain an occluded or blocked needle.

#### **RISK TO HEALTH:**

If an occlusion in the GRIPPER® needle is present, the product will need to be replaced to allow the procedure to continue. This may lead to a delay in the initiation of therapy.

**Smiths Medical has received no reports of deaths or serious injuries related to this issue.**

#### **INSTRUCTIONS TO CUSTOMERS:**

1. Locate and determine the number of affected products in your possession by referring to Attachment 2.
2. Complete the attached Response Form within 10 days and return it to [GRIPPERocclusion2019@smiths-medical.com](mailto:GRIPPERocclusion2019@smiths-medical.com) even if you do not have any of the affected product in your possession.

3. Upon returning the Response Form, Customer Service will provide a shipping label to return the affected product to Stericycle. Include a copy of your completed Response Form inside EACH BOX of returned product to facilitate processing. Ensure boxes are sealed and labeled with your facility name prior to shipping.
4. **DISTRIBUTORS: If you have distributed potentially affected devices to your customers, please immediately notify them of this field removal by providing a copy of this Field Safety Notice and the accompanying Response Form.**

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at [GRIPPERocclusion2019@smiths-medical.com](mailto:GRIPPERocclusion2019@smiths-medical.com).

Sincerely,



G. Barrett, PhD  
VP Quality Systems, Regulatory and Compliance  
Smiths Medical  
6000 Nathan Lane North  
Minneapolis, MN 55442

Enclosures: Attachment 1 – Field Safety Notice (FSN) Response Form, Attachment 2 – Affected Model/Lot List

**ATTACHMENT 1**

**URGENT MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM**

**Potential Occlusion of Individually Sold GRIPPER® Needles and GRIPPER®  
Needles Within PORT-A-CATH®**

Please assist us in executing this Field Safety Corrective Action (FSCA) by completing and returning this Response Form as soon as possible. This will serve as confirmation that you have received and understand the accompanying Field Safety Notice (FSN) and will allow us to ensure that we have reached all customers who may be affected by this issue.

Please complete this Response Form and return it to [GRIPPERocclusion2019@smiths-medical.com](mailto:GRIPPERocclusion2019@smiths-medical.com) within 10 days of receipt.

***\*DISTRIBUTORS - Please provide a copy of this form and the accompanying notice to any of your customers who were shipped affected product.***

Part Number	Lot Number	Quantity to be Returned

*\*Please attach list of any additional if necessary.*

I certify that I have received and understand the information in the attached Field Safety Notice (FSN).

Name and Title (Please Print)	Facility/Hospital and Address	Signature/Date
Email Address	Telephone Number	
Preferred Recall Contact Name	Preferred Recall Email Address	

# GRIPPER® Needles

**GRIPPER®**  
**Non-Coring Needle**

Caution Do Not Reuse

STERILE EO Sterilized using ethylene oxide

Not made with natural rubber latex Do not use if package is damaged.

Non-pyrogenic

REF: **21-2714-24**  
 LOT: **1234X56**  
 Date of Manufacture: YYY-MM-DD

For Placement Only

GTIN: 30610586015780

0.7mm (22 G) × 25mm (1in)

**GRIPPER®** **Non-Coring Needle** **Deltac®**

Aiguille Atraumatique Nicht-stanzende Nadel Ago Non Carotante Aguja Huber Agulha Sem Núcleo  
 Niet-Borende Naald Ikke stansande infusionsnål Ikke-coring nål Ikke Borende nål Ei-leikkaava neula  
 Μη διατρητική βελόνα

20 cm (8 in) Extension Set without injection site (Stainless steel • PVC) Prolongateur sans site d'injection (Ac. Inox • PVC)  
 Verlängerungsleitung Ohne Y-Stück (Edelstahl • PVC) Set di prolunga senza seconda via (Acciaio Inossidabile • PVC) Equipo de extensión sin punto de inyección (Acero inoxidable • PVC) Conjunto de Extensão sem Local de Injeção (Aço inoxidável • PVC)  
 Extensieset zonder aanprik-plaats (Roestvrij staal • PVC) Förlängningsslang utan injektionsport (Rostfritt stål • PVC)  
 Forlængerslange uden Y-Site (Rustfrit stål • PVC) Forlængelsessett uten injeksjonssted (Rustfritt stål • PVC) Jatkoletku ilman injektiokohtaa (Ruostumaton teräs • PVC) Σετ επέκτασης χωρίς θέση ένεσης (Ανοξείδωτος χάλυβας • PVC)

Manufacturer: **Smiths Medical ASD, Inc.**  
 1265 Grey Fox Road  
 St. Paul, MN 55112 (USA)  
 www.smiths-medical.com  
**MADE IN MEXICO**

EC REP European Representative: **Smiths Medical International Ltd.**  
 1500 Eureka Park, Lower Pemberton  
 Ashford, Kent, TN25 4BF, UK

Rx ONLY  
 CE 0473

smiths medical

0.7mm (22 G) × 25mm (1in)

**GRIPPER® Needle- Affected Part Number and Lots**

Part Number	21-2714-24	21-2715-24	21-2718-24	21-2720-24	21-2721-24	21-2733-24	21-2735-24	21-2736-24	21-2737-24	21-2760-24	21-2761-24
Lot	3655327	3674630	3655323	3655322	3666452	3660302	3666448	3660301	3666447	3674592	3655317
	3666475	3675843	3666473	3675832	3675830	3662983	3674618	3662981	3675809	3675803	3662979
	3671671	3677350	3674621	3675833	3675831	3666451	3675817	3674605	3675810	3675805	3671635
	3674631	3716110	3675834	3716101	3715665	3671657	3716071	3675812	3725083	3675807	3675801
	3675844	3725091	3677353	3749587	3725088	3674620	3721132	3675813	3736840	3725081	3721127
	3715667	3749585	3716102	3770692	3731205	3675825	3736842	3716069	3749591	3731191	3725080
	3716111	3770701	3725089		3736849	3675826	3740608	3721130	3757097	3736838	3731190
	3725093		3740631		3740630	3675828	3757100	3736841	3770665	3740605	3740603
	3731211		3757107		3770691	3677354	3770682	3757099		3749593	3740604
	3749579		3770693			3716083		3770669		3757094	3757093
	3749580					3716085				3757096	3770657
	3749581					3725084				3770658	
	3769909					3725085				3770659	
						3740613				3770660	
						3740614					
						3749588					
						3770685					

Part Number	21-2762-24	21-2763-24	21-2764-24	21-2765-24	21-2766-24	21-2767-24	21-2768-24	21-2769-24	21-2770-24	21-2860-24	21-2861-24
Lot	3628112	3653180	3653176	3675785	3653175	3644121	3666421	3628103	3644117	3653165	3653163
	3644124	3666442	3655311	3675786	3655310	3653172	3674552	3653167	3644118	3662976	3653164
	3653181	3674556	3662978	3721123	3666439	3653173	3675773	3655306	3660292	3675762	3671585
	3660300	3675791	3666441	3725073	3671594	3655307	3675774	3660293	3671589	3675763	3671586
	3666444	3675792	3671629	3725074	3675782	3660294	3675775	3666419	3674529	3677382	3674476
	3674569	3675793	3675788	3731176	3675783	3671592	3721087	3671590	3675764	3749624	3675759
	3675797	3731177	3675789	3740596	3721115	3671593	3725064	3675769	3675765	3757073	3675760
	3675798	3731178	3675790	3740597	3725071	3675781	3731172	3675770	3675766	3770599	3675761
	3675799	3731179	3721125		3736824	3757081	3731173	3721081	3722890		3718794
	3722887	3757088	3725075		3736826	3757082	3736809	3725061	3722892		3725057
	3722888	3770647	3736830		3736828	3757083	3736811	3725062	3731169		3731167
	3725079		3740599		3749600	3770622	3749608	3731171	3736804		3736803
	3731181		3749596		3757084	3770625	3749609	3736807	3740561		3740554
	3736835		3757087		3757085		3757079	3736808	3749622		3749625
	3740602		3770641		3770630		3770617	3749611	3757075		3757070
	3749594		3770642		3770632		3770620	3749620	3770605		3770595
	3757089		3770643		3770633			3749621			3770596
	3757092							3757076			3770597
	3770651							3757077			
	3770653							3770612			

Attachment 2: Affected Models/Lots

Part Number	21-2862-24	21-2863-24	21-2864-24	21-2865-24	21-2866-24	21-2867-24	21-2868-24	21-2869-24	21-2870-24	21-2938-24	21-2939-24
<b>Lot</b>	3653162	3655304	3644113	3653160	3644111	3660268	3660266	3666401	3655295	3674151	3660265
	3655305	3671584	3653161	3662974	3655296	3666403	3666402	3675739	3662971	3675694	3666399
	3662975	3675756	3666411	3671582	3666404	3674188	3675742	3675740	3666400	3675695	3671580
	3666417	3718765	3671583	3674341	3671581	3675746	3675743	3675741	3675698	3757059	3675691
	3675758	3736799	3675754	3675751	3675747	3719919	3675744	3718771	3718766	3770544	3675692
	3677384	3749628	3675755	3675752	3675749	3725043	3719918	3725034	3725031		3675693
	3718789	3770589	3677386	3675753	3675750	3731156	3725040	3725036	3725032		3677387
	3719924		3725050	3718788	3718783	3736792	3725041	3731151	3736785		3716061
	3731163		3731162	3725047	3719921	3740539	3731152	3736787	3748504		3719916
	3731164		3736797	3725048	3725044	3748511	3731155	3740535			3725030
	3736801		3748515	3725049	3725046	3757063	3736790	3748506			3740167
	3740552		3770587	3731160	3736794	3770573	3740537				3748498
	3749627			3731161	3740543		3748507				3749629
	3770590			3736795	3748512		3748508				3757058
	3770591			3740545	3757065		3757061				3770537
				3748513	3757066		3770569				3770542
				3757067	3770575		3770570				
				3757068	3770576						
				3770582	3770577						
				3770583							
				3770584							
Part Number	21-2940-24	21-2941-24	21-2946-24	21-2947-24	21-2948-24	21-2949-24	21-2955-24	21-2957-24	21-2960-24	21-2961-24	21-2962-24
<b>Lot</b>	3666398	3660264	3662970	3655291	3662966	3655290	3660254	3655289	3653137	3655288	3675628
	3671579	3674148	3666396	3666395	3662968	3662965	3675643	3662963	3660243	3662962	3675629
	3674150	3675685	3674147	3674146	3671571	3674143	3675644	3675636	3666393	3666391	3719897
	3675687	3716057	3675680	3675675	3674144	3675647	3757047	3675638	3675635	3674138	3731077
	3675688	3736781	3740163	3675676	3674145	3675648	3770488	3736776	3677394	3677395	3731078
	3716059	3749631	3770527	3675677	3675656	3675649	3770489	3757045	3740160	3740158	3740156
	3719913			3716053	3675657	3731145			3748491	3748489	3748486
	3725015			3716055	3675661	3757048			3749634	3757041	3757040
	3736782			3719901	3716016	3770497				3757042	
	3748497			3725011	3725007	3770499				3770479	
	3749630			3725012	3725009					3770480	
	3770530			3725013	3731148					3770481	
	3770532			3731150	3740162						
				3736777	3748492						
				3736779	3757051						
				3740529	3757054						
				3748495	3770502						
				3757056	3770505						
				3770522							

Attachment 2: Affected Models/Lots

Part Number	21-2964-24	21-2965-24	21-2966-24	21-2967-24	21-2968-24	21-2969-24	21-2970-24	21-3251-24	21-3252-24	21-3253-24	21-3256-24
Lot	3644096	3653134	3653133	3653132	3655284	3666385	3674126	3653130	3660230	3636974	3640469
	3653135	3655287	3655286	3671560	3662958	3675356		3653131	3671535	3653128	3644089
	3660242	3662961	3660240	3675373	3671545	3675357		3660232	3674121	3677402	3653126
	3671566	3666390	3662960	3719893	3674127	3677400		3671536	3675731	3740133	3660228
	3674135	3671565	3671564	3731075	3675734	3724997		3674125	3724996		3671534
	3675623	3674130	3677398	3731076	3675735	3731069		3675733	3736763		3674120
	3712296	3675618	3712516	3757034	3675736	3736765		3712515	3740134		3675349
	3725004	3675619	3714560	3770458	3677399	3740136		3719888			3675729
	3725005	3675620	3719894	3770459	3711486	3748471		3731067			3675730
	3748485	3712518	3725000		3711487	3757031		3736764			3724995
		3715979	3736770		3719892	3770445		3740135			3731065
		3719895	3740142		3724998			3748468			3736709
		3725001	3748476		3724999			3748469			3740132
		3725002	3748481		3731074			3757029			3748463
		3736771	3749637		3736768			3770438			3748466
		3740153	3757036		3748473						3757026
		3740154	3770464		3748474						3757027
		3748482	3770468		3749638						3770429
		3749636			3770451						
		3757038			3770453						
		3769880			3770455						
		3769881									
		3769884									
		3769887									
Part Number	21-3257-24	21-3258-24	21-3260-24	21-3261-24	21-3262-24	21-3271-24	21-3272-24	21-3273-24	21-3276-24	21-3277-24	21-3278-24
Lot	3644088	3655283	3628080	3653122	3653121	3644072	3653118	3712501	3675717	3640466	3653111
	3653124	3671531	3653123	3662955	3666375	3653119	3711489		3675719	3644069	3666372
	3666379	3675342	3655282	3666376	3675721	3653120	3719886		3712965	3653113	3675326
	3674119	3677404	3662956	3675337		3660226	3731061		3715972	3660217	3712968
	3675727	3711488	3666378	3677405		3666374	3736702		3719885	3666373	
	3675728	3712507	3671530	3724993		3671529			3724990	3675328	
	3677403	3770427	3675724	3731062		3674117			3740107	3677407	
	3731063		3675725	3748460		3675722			3740111	3712967	
	3736706		3712503	3749658		3677406			3748455	3731059	
	3740130		3712504	3757022		3712963			3749662	3731060	
	3748462		3757023	3770421		3724991			3757021	3740105	
	3749639		3757024	3770423		3740117			3770388	3748452	
	3757025		3770426			3740118				3749665	
						3748458					
						3749660					

Attachment 2: Affected Models/Lots

Part Number	21-3280-24	21-3281-24	21-3282-24	21-3362-24	21-3363-24	21-3364-24	21-3365-24	21-3367-24	21-3368-24	21-3369-24	21-3464-24
<b>Lot</b>	3644068	3653109	3712313	3644064	3653108	3644063	3660204	3653105	3655275	3628069	3628067
	3675324	3660215	3715970	3644065	3666367	3660205	3674992	3655279	3655277	3653101	3653053
	3675325	3674112	3748447	3662951	3674998	3671521	3674993	3660203	3662950	3662947	3655274
	3712969	3675716		3671523	3714643	3674994	3714641	3666363	3674109	3674107	3666360
	3731057			3674111	3715967	3674995	3719883	3671519	3675705	3674981	3674979
	3736696			3675713	3740094	3674996	3724984	3674110	3675706	3674983	3674980
	3748449			3675714	3749675	3674997	3736685	3675709	3675707	3736666	
	3749668			3675715	3757011	3714642	3740064	3675710	3731045	3736667	
	3770381			3714646	3770258	3715964	3757001	3675711	3731046	3740059	
				3719884		3724986	3769911	3714638	3736675	3748427	
				3731053		3731051	3769912	3714639	3740061	3748429	
				3736693		3740065		3714640	3748432	3756991	
				3740095		3740066		3719879	3756992	3769915	
				3748444		3748443		3724978	3756993	3769917	
				3748445		3757008		3731047	3770160		
				3748446		3757009		3731048	3770161		
				3757013		3770171		3736678			
				3770375		3770173		3748435			
						3770175		3749680			
								3756996			
								3756997			
<b>Part Number</b>	<b>21-3465-24</b>	<b>21-3466-24</b>	<b>21-3467-24</b>	<b>21-3468-24</b>	<b>21-3469-24</b>						
<b>Lot</b>	3653051	3653048	3655273	3655271	3655270						
	3660201	3653050	3671517	3662944	3660200						
	3662946	3674972	3674971	3666345	3671504						
	3666353	3674973	3714634	3671505	3674966						
	3674106	3674974	3715956	3674969	3674967						
	3675699	3674975	3731040	3674970	3674968						
	3675701	3677409		3714632	3740047						
	3677408	3714635		3714633	3769925						
	3714637	3715955		3715958	3769927						
	3715961	3719876		3740048							
	3724977	3724976		3740049							
	3731042	3731041		3748407							
	3736663	3740051		3756986							
	3740057	3740052		3770028							
	3748422	3748408		3770030							
	3748424	3749687									
	3756989	3756987									
	3756990	3770035									
	3770039	3770037									
	3770040										

# PORT-A-CATH®

REF 21-4025-24

## PORT-A-CATH®

### Titanium Venous Access System

PolyFlow® Polyurethane Catheter, 1.9mm O.D. (5.8Fr) × 1.0mm I.D., 6Fr Introducer

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**Contenido:** Portal (Titanium and Silicone) with ULTRA-LOCK® Connector • Radiopaque PolyFlow® Polyurethane Catheter, 5.8Fr (1.9mm O.D. × 1.0mm I.D. × 76cm) • 20G (0.9mm) PORT-A-CATH® Needle • 18G (1.3mm) Blunt Needle • Vena Pick • 20G (0.9mm) GRIPPER PLUS® Non-Coring Safety Needle • 20G (0.9mm) 90° PORT-A-CATH® Needle • 18G (1.3mm) Extra Thin Wall Introducer Needle • 6Fr (1.9mm) Introducer (Sheath/Dilator) • 0.035 in. (0.89mm) T\* Guidewire • 2 (12cc) Syringes • Tunneling tool • 3 Point-Lok® Sharps Safety Devices

**Système d'accès veineux. Contenu:** Chambre à cathéter implantable (Ti/Silicone) avec un verrou ULTRA-LOCK® • Cathéter PolyFlow® - en Polyuréthane Radiopaque 5,8Fr (1,9mm Ø ext. × 1,0mm Ø int. × 760mm) • Aiguille PORT-A-CATH® de calibre 20G (0,9mm) (Ac. Inox./Laton/Ni/Cr) • Aiguille épointée de calibre 18G (1,3mm) (Ac. Inox./Laton/Ni/Cr) • Chausse veine (copolymère acétal) à GRIPPER PLUS® de calibre 20G (0,9mm) • Aiguille PORT-A-CATH® coudée à 90° de calibre 20G (0,9mm) (Ac. Inox./Laton/Ni/Cr) • Aiguille introduitrice de 18G (1,3mm) (Ac. Inox./PP) • Introducteur (Gaine/dilatateur) 6Fr (1,9mm) (PEBA/polyéthylène) • Fil guide en J (0,89mm) (Ac. Inox./PTFE) • 2 seringues (12cc) (PP/Isoprène synthétique) • Tunnelisateur (Ac. Inox.) • 3 Point-Lok® Pour Objets Tranchants

**Venöses Zugangssystem. Inhalt:** Port (Titan und Silikon) mit ULTRA-LOCK® Konnektor • Röntgendichten PolyFlow® Polyurethan Katheter, (1,9mm A.D. × 1,0mm I.D. × 76cm) • 0,9mm PORT-A-CATH® Nadel • 1,3mm stumpfe Nadel • Venenschutz • 0,9mm GRIPPER PLUS® nicht stanzennde Nadel • 0,9mm PORT-A-CATH® Nadel (90° geb.) • 1,3mm dünnwandige Einführungsnael • Introducer (Einführbesteck) (1,9mm) • J-förmigen Führungsdraht (0,89mm) • 2 Spritzen (12cc) • Tunnelinginstrument • 3 Point-Lok® Nadelsicherheits Vorrichtung

**Sistema d'accesso venoso. Contenido:** Porta (Titanio y Silicona) con conector de ULTRA-LOCK® (cerradura de aléa) • Catéter de Poliéuretano PolyFlow® Radiopaco, (1,9mm D.E. × 1,0mm D.I. × 76cm) • Aguja PORT-A-CATH® 0,9mm • Aguja despuntada 1,3mm • Selector de vena • Aguja introduidora de pared extra fina de 1,3mm • Introducer (Dilatador de la vena) (1,9mm) • Alambre guía en "J" (0,89mm) • 2 jeringas (12cc) • Instrumento de tunelización • 3 Point-Lok® dispositivo de seguridad para agujas

**Sistema de Acesso Venoso. Conteúdo:** Porta (Titânio e Silício) com Conector ULTRA-LOCK® • Cateter de Poliéuretano e Radiopaco PolyFlow® 5,8Fr (1,9mm DE × 1,0mm DI × 76cm) • Agulha PORT-A-CATH® (0,9mm) • Agulha Romba (1,3mm) • Apontador de Veia • Agulha de Segurança Sem Núcleo GRIPPER PLUS® (0,9mm) • Agulha 90° PORT-A-CATH® (0,9mm) • Agulha Introduçora de Parede Extra-Fina (1,3mm) • Introdutor (Dilatador de Veia) (1,9mm) • Fio-Guia em "J" (0,89mm) • 2 Seringas (12cc) • Ferramenta de Tunelização • 3 Point-Lok® Dispositivo de segurança para agulhas • Objectos Cortantes

**Venusuotiedinningsystem. Inhold:** Port (titanen en silicoon) met ULTRA-LOCK® bevestiging • Radiopaque PolyFlow® polyurethan catheter, (1,9mm E.D. × 1,0mm I.D. × 76cm) • 0,9mm PORT-A-CATH® naald • 1,3mm stompe naald • Venecze aanpriknaald • 0,9mm GRIPPER PLUS® niet-borende veiligheidsnaald • 0,9mm 90° PORT-A-CATH® naald • 1,3mm extra dunwandige introducer naald • Introducer (Huls/dilatator) (1,9mm) • T\* Geleidedraad (0,89mm) • 2 spuit (12cc) • Tunnelnaald • 3 Point-Lok® prikbeschermer

**Venöset system. Innehåll:** Port (titan och silikon) med ULTRA-LOCK®-koppling • Röntgentätt PolyFlow® polyuretankateter (1,9mm YD × 1,0mm ID × 76cm) • 0,9mm PORT-A-CATH®-nål • 1,3mm trubbig nål • Venulångaren • 0,9mm GRIPPER PLUS® icke stanande infusionsnål med nålskydd • 0,9mm 90° PORT-A-CATH®-nål • 1,3mm extra tunn inställningsnål • Introducer (Introducer/dilatator) (1,9mm) • J-formad ledare (0,89mm) • 2 sprutor (12cc) • Tunneleringsverktyg • 3 Point-Lok® säkerhetsanordning för skarpa föremål

**Venost System. Inhold:** Port (Titan og Silikon) med ULTRA-LOCK® lis • Røntgenfætt PolyFlow® kateter (Polyuretan), 5,8Fr (1,9mm U.D. × 1,0mm I.D. × 76cm) • 20G (0,9mm) PORT-A-CATH® Kateternål • 18G (1,3mm) Stump nål • Veneholderen • 20G (0,9mm) GRIPPER PLUS® Ikke-borende nål • 20G (0,9mm) 90° PORT-A-CATH® Kateternål • 18G (1,3mm) Ekstra tynd indsættingsnål • Introducer (Sheath/dilatator) 6Fr (1,9mm) • T\* Guidewire (0,89mm) • To sprøjter (12cc) • Tunneleringsinstrument • 3 Point-Lok® Nålssikkerhedsanordning

**Venekateter. Inhold:** 1 stk. portall (titan og silikon) med ULTRA-LOCK® løbingsøykke • 1 stk. radiopak PolyFlow, polyuretan kateter, 5,8Fr (1,9mm U.D. × 1,0mm I.D. × 76cm) • 1 stk. 0,9mm PORT-A-CATH® nål • 1 stk. 1,3mm uskarp nål • 1 stk. venekåbe • 1 stk. 0,9mm GRIPPER PLUS® butt kanyle nål • 1 stk. 0,9mm 90° PORT-A-CATH® nål • 1 stk. 1,3mm instiksnål for ekstra tynd vægg • 1 stk. Introducerset (Slire/dilatator) 6Fr (1,9mm) • 1 stk. "J" guidewire (0,89mm) • 2 stk. sprøjter (12cc) • 1 stk. tunneleringsinstrument • 3 stk. Point-Lok® sikkerhedsstykker

**Suonen sisääntuomajärjestelmä. Avasaattomat:** Sisääntuomaportti (titaani ja silikoni) ja ULTRA-LOCK®-liitin • Röntgenpositiivinen PolyFlow®-polyuretaanikaatetri, 5,8Fr (UL 1,9mm × SL 1,0mm × 76cm) • 0,9mm PORT-A-CATH®-neula • 1,3mm tylyjä neula • Suonenotin • 0,9mm GRIPPER PLUS® ei-leikkaava turvaneula • 0,9mm 90° PORT-A-CATH®-neula • 1,3mm erittäin ohuet seinämä sisääntuomineula • Sisääntuosi (Holkki/lujennin) (1,9mm) • T\*-johdinanka (0,89mm) • 2 ruiskua (12cc) • Tunnelöintilaitte • 3 Point-Lok®-neulasuojus

**Συστήμα πρόσβασης φλέβας. Περιεχόμενα:** Μία τιτάνη εισόδου (αυτοκλειστή από ττανιοσύλων) με σύνδεση ULTRA-LOCK® • Ένας αετονεκρωτικός καθετήρας πολυουρεθάνης PolyFlow®, 5,8Fr (1,9mm ΕΕ Διὰ × 1,0mm Ιοτ. Διὰ × 76cm) • Μία βελόνα PORT-A-CATH® (0,9mm) • Μία αμβλύα βελόνα (1,3mm) • Μία ακμή για φλέβες • Μία μη κοπρωδής βελόνα ασφαλείας GRIPPER PLUS® (0,9mm) • Μία βελόνα PORT-A-CATH® 90°, (0,9mm) • Μία εξαιρετικά λεπτή βελόνα εισαγωγής τοχωμάτων (1,3mm) • Ένας εισαγωγέας (Lετ Θρωσικό/Διαστολέα) (1,9mm) • Ένα κατεβιγτήριο σύζαγ "J" (0,89mm) • Δύο σύριγγες (12cc) • Ένα εργαλείο διατομής σφραγίας • Τρεκ Point-Lok® Σύστημα ασφαλείας αερίων

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LOT 123456789

2022-02-26

Date of Manufacture: 2017-02-26

GTIN 10610586023804

Caution

Do not reuse

Do not sterilize

STERILE EO

Sterilized using ethylene oxide

Not made with natural rubber latex

Do not use if package is damaged.

Keep dry

Keep away from sunlight

Non-pyrogenic

MR Conditional

Rx ONLY

CE 0086

smiths medical

PORT-A-CATH® - Affected Part Number and Lots											
Part Number	21-4025-24	21-4037-24	21-4051-24	21-4053-24	21-4055-24	21-4065-24	21-4068-24	21-4069-24	21-4071-24	21-4073-24	21-4083-24
Lot	3674105	3659767	3624979	3659766	3683539	3668869	3749691	3765354	3618196	3687796	3662930
	3694006	3674101		3662933	3690396				3740043	3690395	3662931
	3712500	3690401		3731032	3690397					3731024	3662932
	3736641	3694005			3703705					3736575	3756971
	3748406	3703706			3709204						3765346
	3756975	3709205			3712498						3765348
		3731036			3717709						
		3765362			3736577						
					3748401						
					3756973						
					3765356						
					3765357						
					3765358						
					3765360						

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Attachment 2: Affected Models/Lots

Part Number	21-4153-24	21-4155-24	21-4171-24	21-4183-24	21-4187-24	21-4423-24	21-4425-24	21-4437-24	21-4453-24	21-4455-24	21-4465-24
Lot	3628064	3659764	3696520	3731023	3756969	3659762	3696519	3655263	3659761	3643998	3655261
	3674098	3674097	3709202	3736569	3772751	3662929	3717705	3666141	3662927	3662926	3693997
		3687795	3772784	3756970		3666142	3736566	3683517	3712497	3666139	3736554
		3717706				3756968		3694001	3730960	3671489	
		3736572				3765344		3724970	3736565	3674096	
		3776589						3730962	3748382	3687793	
								3748385	3749695	3690392	
								3748386	3765338	3696517	
								3756965		3703702	
										3706172	
										3712495	
										3730957	
										3736563	
										3740039	
										3748380	
										3756963	
										3772703	

Part Number	21-4471-24	21-4474-24	21-4475-24	21-4476-24	21-4477-24	21-4483-24	21-4485-24	21-4873-24	21-8066-24	21-8466-24	21-8468-24
Lot	3703701	3666137	3655257	3655256	3655255	3655254	3679481	3655242	3756945	3662921	3659735
	3717695	3765332	3666126	3659759	3674095	3669980	3683507	3659737		3730943	3666104
	3717696		3709201		3687791	3679144		3693996		3756938	3765319
	3730951		3717694		3690388	3690385		3706169			
	3730952		3736553		3703700	3690386		3730945			
	3756958		3740036		3706171	3696515		3748364			
			3756957		3709200	3703678		3756946			
			3765329		3719958	3706170					
			3765330		3730948	3730946					
					3740035	3736551					
					3748373	3740034					
Part Number	21-8470-24				3756954	3749697					
Lot	3655234					3756952					
	3666103										
	3696513										
	3730942										