

Urgent Field Safety Notice
Carag Bioresorbable Septal Occluder Systems and CBSO Extroducers
Preventive Recall


For Attention of: distributors, physicians, and/or hospitals

| |
|--|
| Contact details of local representative (name, e-mail, telephone, address etc.) |
| Dr. Ajit S. Mallik ajit.mallik@carag.com Phone: +41 41 562 00 74 |
| CARAG AG Bahnhofstrasse 9 6340 Baar, Switzerland |

| 1. Information on Affected Devices | |
|------------------------------------|---|
| 1. | 1. Device Type(s) ASD (Atrial Septal Defect) Occluder |
| 1. | 2. Commercial name(s): Carag Bioresorbable Septal Occluder System |
| 1. | 3. Device Model/Catalogue/part number(s) - Carag Bioresorbable Septal Occluder (REF: 004-846, 004-847, 004-848) - CBSO Extroducer (REF: 005-131) - CBSO Loading Funnel (REF: 006-753) - CBSO Position Controls (REF: 006-951) |
| 1. | 4. Affected serial or lot number range all |

| 2. Reason for Field Safety Corrective Action (FSCA) | |
|---|--|
| 2. | 1. Description of the product problem This is a preventive recall of not yet implanted Carag Bioresorbable Septal Occluders and CBSO Extroducers and not caused due to an incident or a product problem. Patient safety is the most important and as recent reviews showed that certain aspects need to be verified again, not implanted devices are recalled preventively to avoid hazardous situations. For already implanted devices no special actions are required. |

| 3. Type of Action to mitigate the risk | | |
|--|--|-------------|
| 3. | 1. Action To Be Taken by the User | |
| | <input checked="" type="checkbox"/> Complete and return the Field Safety Notice Customer Reply Form <input checked="" type="checkbox"/> Return Devices | |
| | Transmission of this Field Safety Notice This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. | |
| 3. | 2. By when should the action be completed? | 12 May 2021 |
| 3. | 3. Particular considerations for Implantable device: Is follow-up of patients or review of patients' previous results recommended? | No |
| 3. | 4. Is the FSN required to be communicated to the patient /lay user? | No |

| 4. General Information | | |
|------------------------|---|---|
| 4. | 1. FSN Type | New |
| 4. | 2. Manufacturer information (For contact details of local representative refer to page 1 of this FSN/) | |
| | a) Company Name | CARAG AG |
| | b) Address | Bahnhofstrasse 9, 6340 Baar, Switzerland |
| | c) Website address | www.carag.com |
| 4. | 3. The Competent (Regulatory) Authority of Carag has been informed about this communication to customers. | Yes |
| 4. | 4. List of attachments/appendices: | Field Safety Notice Customer Reply Form |
| 4. | 5. Name/Signature | |
| | |  Jérôme Bernhard |