

Briennon, 03/13/2024

**Subject: FSN - SAFETY DATA SHEET FOR A MEDICAL DEVICE – FEMORAL STEMS**














**Ref : AQ2047**

Letter sent by email.

For the attention of materiovigilance correspondent, users, orthopedic surgeons and other healthcare professionals.

**Identification of medical devices:**

The medical devices concerned are the femoral stems listed below:

<b>Reference</b>	<b>Designation</b>	<b>GMDN</b>	<b>UDI</b>	<b>DataMatrix</b>
01-021-01-0007	Evidence Stem HAC Collarless Standard Offset Size 7	34191	03701271001341	
01-021-01-0008	Evidence Stem HAC Collarless Standard Offset Size 8	34191	03701271001358	
01-021-03-0009	Evidence Cemented Stem Stainless steel Size 9	34203	03701271000627	
1-0107807	HAGAP standard stem S7 12/14 collarless	34191	03701271002997	
1-0107808	HAGAP standard stem S8 12/14 Collarless	34191	03701271003000	
1-0108209	HAGAP cemented stem S9 12/14 Collarless	34203	03701271001730	
H45 007	STEMSYS fem stem S7 TI+HA Standard 135° collarless	34191	03760255383699	
H45 008	STEMSYS fem stem S8 TI+HA standard 135° collarless	34191	03760255383705	
H45 C007	STEMSYS fem stem S7 TI+HA Standard 135° collared	34191	03760255389721	
H45 C008	STEMSYS fem stem S8 TI+HA Standard 135° collared	34191	03760255389738	
H45 L009	STEMSYS fem stem S9 TI+HA Offset 128° collarless	34191	03760255383811	
H45 LC009	STEMSYS fem stem S9 TI+HA Offset 128° collared	34191	03760255383910	
H45 R112XL	STEMSYS rev fem stem S12XL std locked TI+HA collared	40125	03760255384382	
H45 S009	STEMSYS fem stem S9 std 135° cemented collarless	34203	03760255384078	
H45 SL009	STEMSYS stem fem S9 Offset 128° cemented collarless	34203	03760255384177	
H45 SL010	STEMSYS fem stem S10 Offset 128° cemented collarless	34203	03760255384184	
H49 007	HACTIV HAC size 7	34191	03760255381114	
H49 008	HACTIV HAC size 8	34191	03760255381121	
H49 S09	Cemented CEMTIV Size 9	34203	03760255381572	
H73 007	STEMSYS HAC Fem. stem S7 standard 135° collarless HAC	34191	03701271000085	
H73 008	STEMSYS HAC Fem. stem S8 standard 135° collarless HAC	34191	03701271000092	
H73 C008	STEMSYS HAC Fem. stem S8 standard 135° collared HAC	34191	03760255384252	

### Reason for Safety Data Sheet:

In order to comply with the new European regulation MDR 2017/745, additional tests were carried out in accordance with the ISO 7206-4:2010 standard.

Following the results of these tests:

- Weight restrictions have been removed
- Weight restrictions must be added or modified as a precautionary measure

This decision is not the result of a safety problem with our implants. In fact, no material vigilance has been recorded concerning breakage of these references since they were placed on the market.

The weight limits are as follows:

<i>Reference</i>	<i>Previous weight limit</i>	<i>New weight limit</i>
01-021-01-0007	75kg	50kg and no head $\geq +7$
01-021-01-0008	75kg	Removal of limit
01-021-03-0009	-	70kg
1-0107807	75kg	50kg and no head $\geq +7$
1-0107808	75kg	Removal of limit
1-0108209	-	70kg
H45 007	75kg	50kg and no head $\geq +7$
H45 008	75kg	75kg and no head $\geq +7$
H45 C007	75kg	50kg and no head $\geq +7$
H45 C008	75kg	75kg and no head $\geq +7$
H45 L009	-	75kg and no head $\geq +7$

<i>Reference</i>	<i>Previous weight limit</i>	<i>New weight limit</i>
H45 LC009	-	75kg and no head $\geq +7$
H45 R112XL	-	75kg and no head $\geq +7$
H45 S009	-	70kg
H45 SL009	80kg	70kg
H45 SL010	-	70kg
H49 007	75kg	50kg and no head $\geq +7$
H49 008	75kg	Removal of limit
H49 S09	-	70kg
H73 007	75kg	50kg and no head $\geq +7$
H73 008	75kg	Removal of limit
H73 C008	75kg	Removal of limit

Insofar as the introduction of the weight restrictions on the labels is due to **a precautionary system** and not to a safety problem with our implants, these new limitations will be applied to our new production batches only. No product recall is necessary.

**No action concerning users is required.**

### To behave :

- Acknowledge receipt of this safety data sheet by returning the page 4
- Send this safety data sheet to the materialovigilance correspondent, users, orthopedic surgeons and other healthcare professionals
- For patients whose weight exceeds the new limit, we recommend you carry out increased monitoring and appropriate physical activity

### Patient risk:

The patient risk is very low. The ISO 7206-4 standard tests do not reproduce normal stress conditions on the implant when it is correctly sized, oriented and implanted. The conditions of the standard reproduce stresses that are more restrictive than the actual stresses in situ. A stress comparable to that of the standard could occur when at least 2 of the conditions of error of dimensioning, orientation and implantation are combined during the installation of the implant. The rare combination of at least 2 of these elements justifies the low risk in terms of frequency of occurrence.

However, it is up to surgeons and other healthcare professionals to determine how implant patients are to be informed.

Contact person :

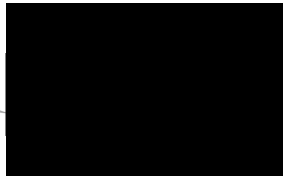
For any questions, you can contact Mrs. Laure Oliver our PRRC (Person Responsible for Regulatory Compliance) 04-77-60-79-99, [qualite@evolutis42.com](mailto:qualite@evolutis42.com) or your distributor.

This information has been declared to the national competent authority and distributed to users and distributors.

Best regards

Jean Michel Peguet  
CEO





Subject: FSN - SAFETY DATA SHEET FOR A MEDICAL DEVICE – FEMORAL STEMS

Ref : AQ2047

## ACKNOWLEDGMENT

I..... the undersigned representative of the company / establishment....., declare that I have read and understood this safety data sheet. I certify that I have sent this safety data sheet to all users of the medical devices concerned.

Date :

Visa :

*This acknowledgment of receipt must be returned to Evolutis by email, fax or post:*

EVOLUTIS  
Service qualité  
10 place des tuilliers  
42720 BRIENNON (France)  
Fax : +33(0)4 77 60 79 90  
[qualite@evolutis42.com](mailto:qualite@evolutis42.com)