February 18, 2026

URGENT SAFETY INFORMATION

Action: Safety-related change to the surgical technique (ST) and instruction for use (IFU)

Affected instrument: HAPTic® rasp proximal sz. 1-5

Our reference no.: FSCA_26001

Dear Sir or Madam,

With this safety information, implantcast GmbH would like to inform you about changes to the surgical technique (ST) and instruction for use (IFU) for the HAPTic® PIP system.

This safety information is provided voluntarily with the aim of further supporting the safe and proper use of the instruments and preventing potential misuse.

This action is not due to a safety issue with the implants.

You are receiving this safety information because you have been supplied with the HAPTic® PIP system from implantcast in the past, to which the changes in the surgical technique (ST) and instruction for use (IFU) listed below now apply.

Surgical Technique (ST)	Reference No.
HAPTic®	HAPTSTxx*

Instruction for use (IFU)	Reference No.
HAPTic® PIP	09300255 xx*

*xx = Placeholder for the respective language or country code

These documents apply to all instruments and sizes of the HAPTic® PIP system.

Background:
In the past, the HAPTic® rasp proximal sz. 1 broke during preparation of the finger joint. In order to further support the safe and proper use of the instruments and to prevent potential misuse, the following changes to the preparation of the finger joint have been included in the surgical technique (ST) and the instruction for use (IFU).

The additions listed below clarify/specify the existing recommendations for use.

Changes in surgical technique (ST)

New warning:
Levering, tilting, or applying lateral forces with the instrument must be avoided, as this may lead to instrument overload and increased risk of instrument breakage.

New note:
In cases of hard or sclerotic bone quality, the intramedullary canal should be opened prior to preparation with the rasp proximal sz. 1 (recommendation: drill max. Ø 2 mm).

Changes in the description of the surgical procedure:
In addition, the surgical technique recommends checking the position of the rasp proximal sz. 1 intraoperatively using imaging. If correction of the entry direction is required, the bone should first be prepared with a drill (max. Ø 2 mm) and subsequently re- prepared with the rasp.

Correction of the rasp position is recommended if implantation of a Haptic® proximal component of sizes 2–5 is planned, as the use of the appropriate rasp prepares the bone bed to the correct size and achieves the required press fit.

If a correction is necessary when planning for implantation of a Haptic® proximal component of size 1, the follow-up treatment may need to be adjusted, as the press fit may be reduced due to enlargement of the medullary cavity.

Changes to the instruction for use (IFU)

New note:
In cases of hard or sclerotic bone quality, the intramedullary canal must be opened prior to use of size 1 rasp (recommendation: drill max. Ø 2 mm).
Levering or application of lateral forces with the rasp must be avoided. If correction of the entry direction is required, this must beperformed using a drill (recommendation: Ø 2 mm); preparation with the rasp is then continued.

Risk assessment/patient aftercare:

This is a precautionary adjustment to the surgical technique (ST) and the instruction for use (IFU).

Hazardous situations		
	Most likely consequence	**Most serious consequence**
Description of **the immediate health consequences** that could result from the use of the product in question or from exposure to it.	During bone preparation with the rasp, mechanical overload (e.g., levering or lateral forces) causes the rasp to break. The breakage is detected intraoperatively and the fragment can be retrieved intraoperatively using appropriate measures. The operation can be continued without a relevant alternative surgical procedure. **Effects on the patient:** No immediate health effects on the patient are to be expected. **Patient follow-up:** No adjusted follow-up required	During bone preparation with the rasp, mechanical overload causes the rasp to break, which is detected intraoperatively. Although the fragment can be retrieved, this results in additional bone loss or a change in the surgical procedure (e.g., prolongation of the operation time, adjustment of the implantation strategy). **Effects on the patient:** The primary stability of the implant restoration may be compromised and requires individual intraoperative assessment. **Patient follow-up:** Adjusted follow-up care depending on the intraoperative situation, e.g., prolonged immobilization or delayed mobilization.

Hazardous situations		
	Most likely consequence	**Most serious consequence**
Description of **the long-term health consequences** that could result from the use of the product in question or from exposure to it.	The breakage of the rasp is detected intraoperatively; however, the fragment **cannot be retrieved without additional bone loss** and remains in the bone or is moved deeper into the medullary cavity using suitable instruments. Treatment with the HAPTic® PIP system is still possible. **Effects on the patient:** No long-term health effects are expected. Based on the biocompatibility and toxicological assessment performed in accordance with ISO 10993-1, ISO 10993-5, and ISO 10993-17, no increased toxicological or biocompatibility-related risk to the patient is to be expected, even if instrument fragments remain in the body for a long period of time. **Patient follow-up:** Informing the patient about the presence of an instrument fragment in the bone. Otherwise, follow-up care should be in line with regular HAPTic® implantation; additional check-ups are only needed if there are clinical abnormalities.	The breakage of the rasp is detected intraoperatively, but the fragment cannot be retrieved and secure implant restoration is not possible. The operation is aborted and no implant is placed during this procedure. **Effects on the patient:** A new surgical procedure on the finger (e.g., arthrodesis or alternative surgical procedure) is necessary. **Patient follow-up:** Informing the patient, temporary immobilization (e.g., splint), wound care, and planning and performing revision surgery according to medical indication.

Measures to be taken:

1. Please read this safety information carefully and ensure that all relevant departments and functionaries are informed of its contents.

2. Please keep this safety information in a safe place.

3. Please complete the enclosed reply form and return it to implantcast GmbH by email to **FSCA@implantcast.de** within **five working days.**

The target date for completion of this action is **March 20, 2026**. Your prompt response will enable us to meet this deadline.

We confirm that we have notified the competent national European authorities of this urgent safety information.

On behalf of implantcast GmbH, we thank you for your help and support in implementing this measure and apologize for any inconvenience.

We would like to assure you that implantcast GmbH is doing everything in its power to ensure that only products that meet your and our high quality standards are on the market.

If you have any questions, please contact our product manager for the **HAPTic® PIP system** or our product management department.

[redacted]

[redacted]

Best regards

implantcast

[redacted]

Managing Director

[redacted]

PRRC-Safety

Please return by email to: FSCA@implantcast.de

Reply form for urgent safety information

implantcast reference no.: FSCA_26001

Surgical technique (ST)	**Reference No.**
HAPTic®	HAPTSTxx*

Instruction for use (IFU)	**Reference No.**
HAPTic® PIP	09300255 xx*

*xx = placeholder for the respective language or country code

- By signing this form, you confirm that you have received the safety information dated February 18, 2025, and that you have read and understood the information contained therein.
- Please **sign** the form and return it by email to: **FSCA@implantcast.de**.

Please note that there have been no changes to the design or manufacture of the HAPTic® PIP system . This is **not a product recall**. It is not necessary to return the product. This safety information only affects the surgical technique (ST) and instruction for use (IFU).

Clinic and address	
implantcast customer number	
Name of contact person	
Function of contact person	
Contact person's phone number	
Date	Signature