



User Manual





















Intelligenza trasparente S.r.l.
Via Soperga, 13
20127 Milano

TABLE OF CONTENTS

1. SYMBOLS	3
2. INTRODUCTION	3
2.1 INTENDED USE	3
2.2 DEVICE DESCRIPTION	4
2.3 DISCLAIMER	4
3. SAFETY PRECAUTIONS	4
4. PRODUCT MATERIAL INFORMATION	5
5. ISTRUCTION FOR USE	5
5.1 POSSIBLE ADVERSE EFFECTS	5
6. ENVIROMENTAL CONDITIONS AND DISPOSAL MODES	5

1. SYMBOLS


	Manufacturer		CE mark
	Lot number		Date of manufacture
	Expiration date		e-IFU Indicator
	Do not re-use		Do not re-sterilize
	Sterilized using ethylene oxide		Do not use if package is damaged
	Temperature limit		Keep dry
	Humidity limitation		Caution
	Medical Device		Unique Device Identifier
	Single sterile barrier system with protective packaging outside		Catalogue number


2. INTRODUCTION

Before proceeding with use, carefully read this manual. Always keep this manual within reach.

User manual is sent by email to the final user by authorized personnel by INtelligenza Trasparente Srl. A paper version of the User Manual can be provided by Intelligenza Trasparente Srl by sending an email request to info@brain-intra.com. The paper version of the User Manual will be sent within 7 calendar days after receiving the request. The information and illustrations contained in this manual are updated to the date of publication indicated in the page footer.

To prevent harm to persons or damages to objects, read all the “Safety precautions” included in this user manual at paragraph 3. Depending on their degree of seriousness, the safety precautions are classified with the following indications:

 **Caution:** referred to precaution that, if ignored, may cause minor or moderate injury.

 **Warning:** referred to precaution that, if ignored, can cause death or serious injury.

2.1 Intended use

INTRA is an ultrasound transparent cranial prosthesis intended for the restoration of bony defects in non-weight bearing cranial applications.

The final user of INTRA is a neurosurgeon.

2.2 Device description

INTRA is a polymeric cranial prosthesis, ultrasound transparent and easy to work with. It comes in three standard formats but can be shaped, carved and feathered intra-operatively with standard surgical instruments directly on the sterile field for an excellent final fit.

No pre-placing of preinstalled fixation plates are needed, since INTRA prosthesis is designed to be easily drilled and fixated, and is compatible with standard screws and plates, allowing a more flexible approach for the operating surgeon.

INTRA surgical implants can be modified with a variety of surgical instruments. Implants may require fitting to the defect area at the time of surgery. The implant edges can be delicately shaped and feathered for a smoother transition from the implant to the patient's own bony contour.

This manual is relative to the following models of INTRA prosthesis:

- CS000: Intra c-shaped small, 60x3x4 mm, sterile
- CL000: Intra C-shaped large, 80x120x4 mm, sterile
- SL000: Intra S-shaped large, 80x120x4 mm, sterile

2.3 Disclaimer

The manufacturer, Intelligenza Trasparente s.r.l., disclaims any liability, expressed or implied, and cannot be considered responsible for harms or damages and personal injury arising out or connected with any error in the use of the device and its accessories. The manufacturer, Intelligenza Trasparente s.r.l., shall be under no liability, expressed or implied, with respect to any damages (personal injury and/or damage to property) which might arise or be caused, whether by the customer or by any of the users of the product, and its accessories, as result of:

- Use of the device in modalities or during procedures different from those specified in the intended use of the product
- Device storage and preservation in environmental conditions not compliant with the indication reported
- Device used not in compliance with the instructions and precautions reported in this user manual
- Improper use or incorrect intervention
- Any attempt to tamper with the device, under any circumstance

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Intelligenza Trasparente s.r.l. does not provide medical advice or services. The treating physician is responsible for determining, based on his knowledge and the characteristic of the particular case, the appropriate technique and treatment. The physician is also responsible to inform the patient about potential risks, complications and benefits of certain products and procedures.

3. SAFETY PRECAUTIONS

⚠ Warning

- INTRA prostheses are provided EtO sterile and individually packed. Carefully check the packaging before opening it. If the packaging is damaged, do not use the contained device under any circumstance. Failure to observe this precaution may result in serious harm or death of the patient.
- INTRA prostheses are intended for **single use** only. Failure to observe this precaution may result in serious harm or death of the patient.
- Carefully check each prosthesis before using it. In case of abnormalities, dispose of the prosthesis and replace it with a new one. Failure to observe this precaution may result in serious harm to the patient.
- Do not use INTRA after the expiration date reported on the label. Failure to observe this precaution may result in serious harm or death the patient.
- Do not place or carve the implant on surgical drapes, surgical clothing or any other surface that may contaminate the implant with lint and other particulate matter.
- INTRA surgical implants are provided sterile and **should not be re-sterilized**
- Preparation for implant use should be in a sterile environment. Implants should remain in its protective package until ready for surgery.
- INTRA implants are not designed for use in weight bearing or load bearing applications.

⚠ Caution

- Improper fixation of the plates and screws for prosthesis fixing may result in the formation of a ridge.
- Select the appropriately sized prosthesis, plates and screws for the patient.
- If needed, adapt the prosthesis pre-operatively to reach a perfect fit

- Responsibility for proper selection of patients, adequate training, experience in the choice and placement of prostheses & screws rests with the surgeon.
- Delayed healing, nonunion or subsequent bone resorption or trauma may cause excessive stress on this device and result in loosening or fracture.
- Selection of plate and screw size must be carefully considered by the operating surgeon. Quality of the bone, bone type, functional loads exerted on bone(s), and post-operative patient compliance should all be taken into consideration.

4. PRODUCT MATERIAL INFORMATION

INTRA implants are manufactured from a polyolefin material, 100% biocompatible.

5. ISTRUCTION FOR USE

The device is provided packed in medical eto-compatible double envelopes, heat-sealed. Open the secondary envelope just before the intervention. The sterile barrier is constituted only by the internal package.

The specific installation technique is chosen by the treating physician when performing the intervention.

The device has to be fixed by means of titanium plates and screws or non-absorbable suture wire (not included in the package) after proper drilling. The prosthesis can be retouched directly by the surgeon in the operating room to fit the patient's bone defect. Following carving or trimming, thoroughly rinse the implant in sterile saline to remove any loose particles.

Inform the patient about any possible risk related to the intervention, limitation of the implant and postoperative care and rehabilitation.

Implants shall be fixed on the bone and not having direct contact with the central nervous system. To avoid contact, ultrasound compatible dura substitutes may be used.

It is up to the surgeon's discretion whether or not to use INTRA implants in the following cases: pregnant women, lactating mothers, or when the patient has not reached full growth. INTRA implants are not intended for pediatric/neonatal use.

5.1 Possible adverse effects

Adverse results may be clinically related rather than implant related.

- Possible adverse effects are the following:
- Osteoporosis, osteolysis, osteomyelitis, infection or inhibited revascularization and poor bone formation can cause loosening, bending, cracking and fracturing of the device or premature loss of fixation with the bone, leading to nonunion.
- Delayed or nonunion, which may lead to breakage of the implant.
- Infection, early or late, both deep and/or superficial.
- Migration, bending, fracture or loosening of the implant.
- Pain, discomfort, or abnormal sensation due to the presence of the device
- Increased fibrous tissue response around the fracture site and/or the implant
- Necrosis of bone
- Inadequate healing

6. ENVIROMENTAL CONDITIONS AND DISPOSAL MODES

Storage conditions (long term)	Temperature from 10°C to + 30°C Relative humidity from 30% to 70%
Short term storage conditions (e.g. transport) max 3 weeks	Temperature from -20°C to + 60°C Relative humidity from 10% to 90%

⚠ **Caution** Keep away from any source of degradation such as sunlight, UV-lamps, chemicals (direct or indirect contact), ionizing radiation and flames.

Single-use components and materials that entail a biological risk shall be disposed according to the local regulations in force concerning hospital wastes.

The English version of this user manual is the original document from which all the translations have been obtained. In case of any inconsistencies, the English version matters.

This document is proprietary and confidential.
Unauthorized reproduction or distribution is a violation of federal and state laws.