KONFORMITÄTERKLÄRUNG
DECLARATION OF CONFORMITY
CERTIFICAT DE CONFORMITÉ
DICHIARAZIONE DI CONFORMITÀ
DECLARACIÓN DE CONFORMIDAD
DECLARAÇÃO DE CONFORMIDADE

Produkt / Product / Produit / Prodotto / Producto / Produto

SR Ivocap 3

DE Hiermit erklären wir in alleiniger Verantwortung, dass das oben aufgeführte Produkt den erwähnten Normen entspricht. Gemäß den Bestimmungen der EU-Richtlinie(n):

GB We herewith declare that the product listed above complies with the mentioned standards. Following the provisions of Directive(s):

FR Par la présente, nous déclarons que le produit ci-dessus indiqué est conforme aux normes énoncées. Conformément aux dispositions de la (des) Directive(s) CE:

IT Con la presente dichiariamo sotto la nostra responsabilità, che il prodotto sopra menzionato corrisponde alle norme citate. Secondo le disposizioni della/e Direttiva/e CEE:

ES Por la presente declaramos que el producto arriba indicado cumple con las normas citadas. Siguiendo las indicaciones de la Directiva:

PT Declaramos que o produto citado cumpre as normas mencionadas. De acordo com as especificações da(s) Diretriz(es):

<table>
<thead>
<tr>
<th>EN 292-1</th>
<th>1991</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 292-2-A1</td>
<td>1996</td>
</tr>
<tr>
<td>EN 294</td>
<td>1992</td>
</tr>
<tr>
<td>EN 349</td>
<td>1993</td>
</tr>
</tbody>
</table>

Schaan, 02.12.2003

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Rev. 1.2
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Views of the Equipment System, List of Parts

A) Pressure apparatus “ID3”
A1 = Locking valve
A2 = Manometer
A3 = Extrusion piston
A4 = Vise shank
A5 = Safety loop

B) Clamping frame “JS4”
B2 = Thrust collar with lever
B3 = Pressing plate

C) Flask
C1 = Flask half M
C2 = Flask half W
C3 = Flask lid
C4 = Injection funnel

D) Capsule plunger
E) Investment aid
F) Funnel
G) Timer
1. Introduction

The SR Ivocap System is an injection technique which has been especially developed to compensate curing shrinkage. Heat/pressure curing allows shrinkage of the acrylate during polymerization to be compensated by inflowing material.

The SR Ivocap injection technique, therefore, permits the fabrication of high quality products with excellent physical properties.

Indication
- Complete dentures
- Partial dentures
- Retainers
- Orthodontic appliances
- Occlusal splints

Contraindication
Keep unpolymerized material away from intraoral areas. Do not use the material if the patient is known to be allergic to any of the ingredients listed.

The SR Ivocap System may only be operated by trained personnel.

1.2 Signs and symbols

The signs and symbols in these Operating Instructions facilitate the finding of important points and have the following meaning:

- Risks and dangers
- Important information
- Contraindication

1.3 Notes regarding the Operating Instructions

These Operating Instructions must be read prior to working with the SR Ivocap System.

Equipment concerned:
SR Ivocap System Target group: Dental technologists

The Operating Instructions facilitate the correct and economic use of the SR Ivocap System.

These Operating Instructions are divided in several, clearly structured chapters. They should enable you to locate specific topics quickly and easily.

The SR Ivocap material is not described in these instructions. Please refer to the corresponding Instructions for Use of the Ivocap material.

The information about risks/dangers, important information, and contraindications, these Instructions contain corresponding signs/symbols (pictographs) to mark important paragraphs.

We recommend keeping the Instructions in a safe place near the equipment to have immediate access to the information if necessary.

Should you lose the Operating Instructions, extra copies can be ordered at a nominal fee from your local Ivoclar Vivadent Service Center.
2. Safety First

This chapter is especially important for personnel who work with the SR Ivocap System or who have to carry out maintenance or repair work. This chapter must be read and the corresponding instructions followed.

2.1 Indications

The SR Ivocap System must only be used for injecting the SR Ivocap material and it should be used for this purpose only. Other uses than the ones stipulated, i.e. injecting other materials, etc. are contraindicated. The manufacturer does not assume any liability for damage resulting from misuse. The user is solely responsible for any risk resulting from failure to observe these Instructions.

Further instructions to assure proper use of the system:

– The instructions, regulations, and notes in these Operating Instructions must be observed.
– The system must be operated under the indicated environmental and operating conditions (Chapter 9).
– The SR Ivocap System must be properly maintained (Chapter 7).

2.1.1

Risk of crushing

Do not reach between pressing plunger and safety loop with your fingers. There is a risk of crushing when air is compressed.

2.1.2

Burn hazard

Use protective thermo-gloves to touch hot metal parts.

2.1.3

Burn hazard

Do not use the water bath without the plastic floaters. Splash water presents a burn hazard.

2.1.4

Burn hazard

Wear protective clothing to protect yourself from splash water.
3. Product Description

3.1 Components

The SR Ivocap basic assortment consists of the following components:
- Pressure apparatus
- Flask
- Clamping frame
- Capsule plunger
- Investment aid
- Funnel
- Compression spring
- Allen key

Furthermore, the following accessories are required (not contained in the assortment):
- Cap Vibrator (Ivoclar Vivadent)
- Polymerization bath (various manufacturers)
- Hydraulic press (various manufacturers)
- Plastic floaters (Ivoclar Vivadent)

3.2 Hazardous areas and safety equipment

Description of the risk areas of the SR Ivocap System:

<table>
<thead>
<tr>
<th>Hazardous area</th>
<th>Type of risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flask and clamping frame</td>
<td>There is a burn hazard if the equipment is removed from the boiling water without protective gloves.</td>
</tr>
<tr>
<td>Splash water from the polymerization bath</td>
<td>There is a burn hazard if no protective clothing and gloves are worn.</td>
</tr>
</tbody>
</table>

See also Chapter 2.

3.3 Functional description

The SR Ivocap System is an injection technique which has been especially developed to compensate curing shrinkage. Controlled polymerization allows shrinkage of the material during polymerization to be compensated by inflowing material. The SR Ivocap injection technique, therefore, permits the fabrication of high quality products with outstanding physical properties.

3.4 Accessories

- Cap Vibrator (Ivoclar Vivadent)
- Wall bracket for 4 pressure apparatus (e.g. from BDT)
- Polymerization bath (e.g. from BDT)
- Hydraulic press (various manufacturers)
- Various accessories (BDT)

Address of BDT:
BDT GmbH, Industriestrasse 27, D-77656 Offenburg (Germany)
4. Installation

4.1 Unpacking and checking the contents

Remove system components from their packaging and place them on a suitable table.

Check the delivery for completeness (see delivery form in Chapter 9) and transportation damage. If certain parts are damaged or missing, contact your local Ivoclar Vivadent Customer Service. We recommend keeping the original packaging for future transportation purposes.

4.2 Selecting the location

The diagram below depicts one possible installation.

**Important information**

For safety reasons, the installation of the pressure, power, and water connections may only be carried out by qualified technicians (electricians, plumbers).

Furthermore, the national installation requirements of the corresponding country must be observed.
5. Operation

5.1 Operating elements on the pressure apparatus

Compressed air locking valve (A1)
This locking valve is used to close or open the pressure cylinder for the compressed air.

Operation:
- Locking valve open: perpendicular position
- Locking valve closed: horizontal position

Safety loop (A5)
The safety loop is used to secure the vise shanks.

Operation:
- Safety loop open: Towards the pressure cylinder
- Safety loop closed: Towards the clamping frame

5.2 Operating elements on the clamping frame

Thrust collar with lever (B2)

Operation:
1) Thrust collar with lever closed (push to the right until it stops)
2) Thrust collar with lever open (push to the left)

Pressure onto the clamping frame: 3 tons
6. Procedure

6.1 Practical use

The most important steps:

1. Injection - 5 minutes
2. Polymerization – 35 minutes in boiling water (as of the beginning of boiling)
3. Cooling in a cold-water bath – at least 30 minutes; the injection pressure must be maintained for at least 20 minutes thereof

For information on how to process the material please refer to the material Instructions for Use of the SR Ivocap System.
7. Maintenance, Cleaning, and Diagnosis

This chapter describes the maintenance and cleaning procedures which can be carried out by dental professionals. All other tasks must be performed by qualified service personnel at a certified Ivoclar Vivadent Service Center.

7.1 Monitoring and maintenance

The time for these maintenance procedures depends on the frequency of use and working habits of the users. For that reason, the recommended times are only approximates.

<table>
<thead>
<tr>
<th>What:</th>
<th>Part:</th>
<th>When:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check all compressed air</td>
<td>Compressed air connections</td>
<td>Before use</td>
</tr>
<tr>
<td>connections for correct fit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check the components for</td>
<td>Pressure apparatus</td>
<td>Before use</td>
</tr>
<tr>
<td>mechanical damage</td>
<td>Flasks, clamping frame</td>
<td></td>
</tr>
<tr>
<td>Check the plastic parts of</td>
<td>Plastic parts of the flask</td>
<td>Before use</td>
</tr>
<tr>
<td>the flask for correct fit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean contaminated clamping</td>
<td>Clamping frame</td>
<td>in case of</td>
</tr>
<tr>
<td>frame (wax), e.g. by boiling</td>
<td></td>
<td>contamination</td>
</tr>
<tr>
<td>out</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Disconnect power and compressed air connection before maintenance and cleaning.

The insulation shoulder of the flask must only be replaced by a certified Service Center, since remounting requires a special mounting assembly and a special material. Only the correct mounting procedure ensures sound function of the flask.

7.2 Cleaning

Metal parts can be cleaned with warm water and a cleaning brush. After cleaning, the flask may be treated with Vaseline to facilitate the removal of plaster residue.

7.3 Changing the Compression spring

Please take note of the informational sheet added to the ‘spring washers’ set.

The Compression spring are to be changed by a certified Ivoclar Vivadent Service Center.
8. What if...?

This chapter will help you to recognize malfunctions and take appropriate measures or, if possible, to perform some repairs.

8.1 Error messages

List of possible error messages and their meaning:

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Notes for users</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Flasks do not close. The flask covers do not sit on the flask margins.</td>
<td>Flank margins are not clean; plaster residue on the injection funnel.</td>
</tr>
<tr>
<td>2</td>
<td>The model to be invested does not fit in the flask.</td>
<td>The model should be trimmed prior to investment.</td>
</tr>
<tr>
<td>3</td>
<td>The pressure is difficult to be transferred to the flask and/or clamping frame.</td>
<td>Clamping frame is not correctly positioned, i.e. in the centre of the press.</td>
</tr>
<tr>
<td>4</td>
<td>Pressure in the clamping frame fluctuates.</td>
<td>Compression spring in the clamping frame are old or dirty and cannot transfer the pressure. Replace the compression spring or clean the clamping frame (see Error 12).</td>
</tr>
<tr>
<td>5</td>
<td>Injection plunger enters the capsule and deforms the bottom of the capsule. The material is extruded at the wrong end of the capsule.</td>
<td>The injection plunger is not correctly placed on the capsule. There is an empty space between the injection plunger and capsule bottom. Avoid empty space and place the injection plunger evenly on the capsule bottom.</td>
</tr>
<tr>
<td>6</td>
<td>The rod of the injection plunger cannot be moved, even if the connection to the compressed air source is interrupted. It seems to be stuck.</td>
<td>Negative pressure in the pressure cylinder may prevent the plunger from moving, open valve</td>
</tr>
<tr>
<td>7</td>
<td>Injection plunger does not move. The SR Ivocap material is not injected.</td>
<td>– No compressed air present – Capsule cover was not removed – There is plaster residue or the funnel is blocked, e.g. by plaster residue – The injection channels are too narrow. – The flow properties of the resin are poor because of incorrect storage</td>
</tr>
<tr>
<td>8</td>
<td>The resin flows out of the flask during polymerization.</td>
<td>– Leaks as a result of incorrect investment. – Flask defective. – Inadequate clamping pressure on the frame. – A foreign object is stuck between the two flask halves.</td>
</tr>
<tr>
<td>9</td>
<td>The locking mechanism is blocked.</td>
<td>The mechanical components are damaged as a result of improper handling. In case of considerable damage, the mechanical components must be replaced.</td>
</tr>
<tr>
<td>10</td>
<td>The locking mechanism is contaminated with wax.</td>
<td>Wax residue in the water bath has contaminated the clamping frame. Boil out clamping frame with clean, hot water.</td>
</tr>
<tr>
<td>11</td>
<td>Capsule reservoir has polymerized after 35 minutes.</td>
<td>– Water level surpasses the marking on the clamping frame. – An unsuitable polymerization bath was used. – The system was not placed in cold water immediately after polymerization. – Reduce polymerization time by 1–2 minutes if necessary</td>
</tr>
</tbody>
</table>

8.2 Repairs

Repairs may only be carried out by a certified Ivoclar Vivadent Service Center. Please refer to the addresses in Chapter 10.

If repairs during the warranty period are not carried out by a certified Ivoclar Vivadent Service Center, the warranty will expire immediately.

Please also read the safety information in Chapter 2.
9. Product Specifications

This chapter contains all relevant product specifications.

9.1 Delivery form

1 Pressure apparatus
1 Clamping frame
2 Flasks
1 Timer
1 Compression spring
1 Capsule plunger
2 Investment aids
1 Allen key

9.2 Technical data

<table>
<thead>
<tr>
<th>Item</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flask</td>
<td>1.3 kg</td>
</tr>
<tr>
<td>Clamping frame JS4</td>
<td>2.3 kg</td>
</tr>
<tr>
<td>Pressure apparatus ID3</td>
<td>2.0 kg</td>
</tr>
<tr>
<td>Total</td>
<td>5.6 kg</td>
</tr>
</tbody>
</table>

Max. operating pressure:

<table>
<thead>
<tr>
<th>Item</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure apparatus</td>
<td>6.5 bar</td>
</tr>
<tr>
<td>Clamping frame</td>
<td>3 tons</td>
</tr>
</tbody>
</table>

Noise emissions:

< 70 dB (A)

9.3 Acceptable operating conditions

Acceptable humidity range
Maximum relative humidity at 31 °C (87 °F) gradually decreasing to 50% at 40 °C (104 °F), condensation excluded.

Acceptable ambient pressure
The unit is tested for altitudes of up to 2000 m above sea level.

9.4 Acceptable transportation and storage conditions

Acceptable temperature range
-20 °C to 50 °C (-4 °F to 122 °F)

Acceptable humidity range
Maximum relative humidity at 31 °C (87 °F) gradually decreasing to 50% at 40 °C (104 °F), condensation excluded.

Acceptable ambient pressure
500 mbar to 1060 mbar

Use only original packaging together with the respective foam material for shipping purposes.
This apparatus has been developed solely for use in dentistry. Start-up and operation should be carried out strictly according to the Instructions for Use. Liability cannot be accepted for damage resulting from misuse or failure to observe the Instructions. The user is solely responsible for testing the apparatus for its suitability for any purpose not explicitly stated in the Instructions. Descriptions and data constitute nor warranty of attributes and are not binding.