OMNIA®
Disposable Medical Devices
www.omniaspa.eu - info@omniaspa.eu

Omnia Srl - Via F. Delnevo, 190 sx
I - 43036 Fidenza (PR) - Italy
tel +39 0524 527453 - fax +39 0524 525230
Cod. Fisc/Part. IVA/Reg.Imp.: IT 01711860344
R.E.A. PR 173685 - Capitale sociale i.v. € 200.000,00

Urgent Medical Device Recall

Product Description	Part Number	Expiration Date Range
Soft Tissue Punches	32.Z2000.00, 32.Z2002.00, 32.Z2004.00, 32.Z2006.00, 32.Z2007.00, 32.Z2008.00, 32.Z2009.00, 32.Z2020.00, 32.Z2022.00, 32.Z2024.00, 32.Z2026.00, 32.Z2027.00, 32.Z2028.00, 32.Z2030.00, 32.Z2032.00, 32.Z2034.00, 32.Z2036.00, 32.Z2038.00, 32.Z2040.00, 72.T1950.00, 72.T1951.00, 72.T1952.00, 72.T1953.00	02Jan2021 through 31Dec2025

Date: 25 March 2021

Dear Valued Customer,

This letter is to inform you of a recall of Omnia Soft Tissue Punches due to a potential sterilization discrepancy.

Reason for Recall
Omnia has been made aware of a situation at a contract sterilization facility regarding inadequate or inappropriate sterilization processes being followed by employees of the contract sterilizer. This could result in the potential for impacted product labeled as sterile to be non-sterile before patient use. Patient harm has not been reported as a result of this situation.

Actions to be taken by Omnia Customers:
1. Quarantine and discontinue use of all Omnia Soft Tissue Punches.
2. Contact Omnia Customer Service at +39 0524 527453 with any questions. For replacement product, please reach out to your Sales Representative or Omnia Customer Service.
3. Please return the enclosed Acknowledgment Form with completed information to Alessandra Cesari, Recall Coordinator, via email at Alessandra.cesari@omniaspa.eu.
4. If this product was further distributed, please notify your customer of this recall.

We sincerely apologize for any inconvenience this situation may cause you or your customers.

Alessandra Cesari
QA Responsible

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Soft Tissue Punch Recall Acknowledgment Form

Product Code(s)	Lot(s)	Quantity of Soft Tissue Punches in inventory

Name of Organization: _____

Organization Address: _____

Contact Name: _____

Email: _____

Phone: _____

Please return this form to Alessandra Cesari via email at alessandra.cesari@omniaspa.eu.