

A Two-Stage Encapsulation Procedure for Sterilization-Resistant MEMS Devices With Integrated SMA Actuator

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Summary:

In this paper we propose a wafer level encapsulation approach for heterogeneous integration of SMA wire actuators at low temperatures. The approach is based on the combination of anodic pre-bonding and laser bonding. For the first time, a MEMS-based sterilization counter device was realized withstanding the harsh conditions associated with cleaning and sterilization procedures applied for medical instruments. A reliability of up to 93% was achieved for recording of 125 performed reprocessing cycles.

Keywords: Heterogeneous integration, SMA wire actuator, sterilization counter, laser bonding

Introduction

Reprocessing of reusable medical instruments requires a critical, multi-stage process in order to remove all organic debris and microbial life. Key steps include cleaning, disinfection and sterilization. Due to the high thermal load acting on the medical instruments during sterilization, there is a demand to monitor the number of times a product has been sterilized [1]. However, detection and recording of sterilization events on individual medical devices remain a challenging task [2]. Electronic, battery-based data loggers available on the market are too large in size and too expensive for integration on instrument level [3].

A new concept for autonomous sensing of sterilization events on medical instruments was proposed by Pagel et al. and is based on a micro-mechanical system with an integrated shape memory alloy (SMA) actuator [4]. Heterogeneous integration of standard SMA wires into silicon microstructures was demonstrated by Hoffmann et al. [5]. However, achieving a robust encapsulation remains a major challenge, as the SMA material limits processing temperatures to approximately 200°C. Adhesive bonding techniques have failed so far, as the robustness in the autoclave has proven to be very limited with a maximum cycle count below 20.

In this paper we propose a novel wafer level approach for robust encapsulation of SMA wire actuators. This approach enables MEMS devices withstanding the harsh conditions associated with cleaning and sterilization of medical instruments. For the first time, a robustness of 125 sterilization cycles has been demonstrated. The

new approach enabled to characterize functional prototypes of the sterilization cycle counter device inside a steam autoclave giving valuable findings about performance and reliability.

Materials and Methods

The micromechanical counter system is realized in the device layer (100 µm thickness) of an SOI wafer. A specific feature of the device is, that the gear wheel and the embedded SMA wire actuator (76 µm diameter) are loose elements. Consequently, special procedures are required, in particular for encapsulation of the device. The silicon device wafer and the glass cap wafer are aligned using a standard mask aligner. However, the glass wafer needs to be loaded first in upside-down orientation. Consequently, after alignment of the wafers on the bond chuck, the silicon wafer is facing up with its bottom side. This means, there is no optical access for direct laser bonding. Therefore, an anodic pre-bond is performed with temperatures below 200°C. The voltage is set to be very low (< 300 V) in order to prevent sticking of the gear wheels on the glass wafer. The anodic prebond is strong enough for handling the wafer stack without debonding or

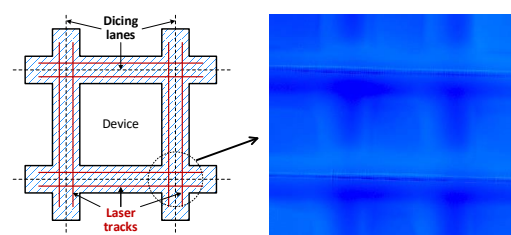


Fig. 1. Left: schematic view of bond frame and scan pattern; Right: laser bond tracks in the glass wafer

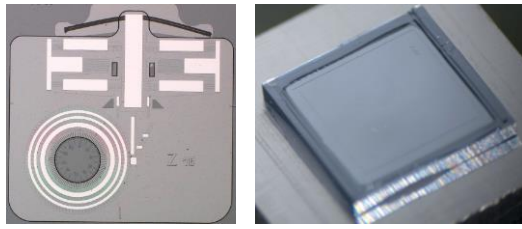


Fig. 2. Left: encapsulated device with integrated SMA wire actuator; right: test chip after tensile test

dealignment. After prebonding, the final bond is generated by using a continuous wave Laser with a wavelength of 1070 nm. The spot size is 200 μm and the Laser power is controlled by a Pyrometer. The travelling speed of the Laser spot is 2 mm/s. The wafer stack is bonded by scanning a grid-like pattern generating a bond frame for each chip (Fig. 1 left). The tracks of the laser bond lines that form in the glass wafer, are shown in Fig. 1 right. The wafer is then conventionally diced to release individual chips (Fig. 2 left). To determine the bond strength, specific test chips were characterized using a standard tensile test. The sterilization resistance of the encapsulation was accessed by performing 50 and 125 reprocessing cycles including cleaning and disinfection with chemical agents as well as steam sterilization at 134°C for up to 10 minutes.

Results and Discussion

The tensile test revealed a well-defined fracture pattern (Fig. 2 right) indicating a solid bond between the wafers in the region of the bond frame. Fig. 3 shows the fracture strength of 8 samples (mean value and standard deviation) for different wafers of a test series. By tuning and optimizing relevant parameters of the process chain (pretreatment, anodic prebonding and laser boning), the fracture strength is significantly increased. In particular, the pretreatment of the silicon device wafer, starting with wafer R2W12, has a significant effect. For comparison, the fracture strength of laser welded glass chips with equal geometry is also shown (Lighthfab). The behavior of encapsulated devices is shown in Fig. 4. After 125 reprocessing cycles, counter devices showed no signs of moisture ingress, confirming a steriliza-

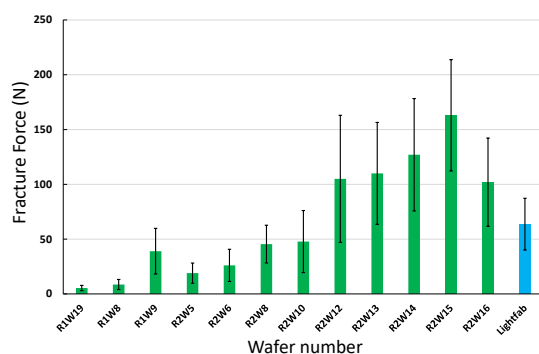


Fig. 3. Fracture strength for different wafers of a test series with variable process parameters

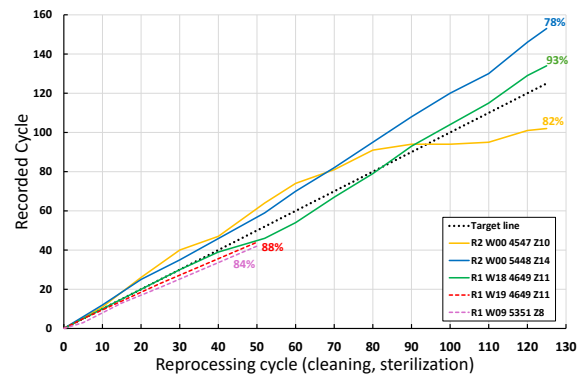


Fig. 4. Characterization of counter devices: number of recorded cycles vs number of cycles performed.

tion-resistant encapsulation. The reliability of recording performed sterilization cycles is currently up to 93%. Counting errors are caused by a variation of the switching point. Further research is required to reduce the impact of tolerances and to achieve a more reliable device behavior.

Conclusions

The presented results demonstrate the feasibility of a two-stage encapsulation process for heterogeneous integration of SMA wire actuators at low temperatures without damaging the SMA material. Through tests in the application environment, a sterilization-resistant encapsulation was verified. For the first time, a MEMS-based sterilization counter device was realized withstanding 125 reprocessing cycles. The reliability of counting sterilization cycles reached a maximum of 93%. The successful integration of SMA wire actuators opens up new sensor- and actuator applications beyond the sterilization cycle counter.

References

- [1] European medical device regulation (EU-MDR), www.eumdr.com
- [2] E. A. Jacuzzi et al., Novel sterilization counter for medical applications, *Proceedings SMST 2010*
- [3] L. Boehler et al., Sensors in the Autoclave-Modeling and Implementation of the IoT Steam Sterilization Procedure Counter; *Sensors* 2021, 21, 510; doi: 10.3390/s21020510
- [4] K. Pagel et al., Development of a shape memory alloy actuator for a micromechanical sterilization cycle counter, *Proceedings SMASIS 2020*; doi: 10.1115/SMASIS2020-2242
- [5] D. Hoffmann et al., Hybrid Integration of A Shape Memory Alloy Actuator For Micro Thermal Mechanical Systems, *Proceedings IEEE MEMS* 2022; doi: 10.1109/MEMS51670.2022.9699649

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